## AMENDMENTS TO THE CLAIMS

Please amend the claims as follows:

1. (Currently Amended) A method for the treatment of a disease in a mammalian subject comprising administering to said subject an effective amount of a mammalian intermediary metabolite, wherein said intermediary metabolite is a β-glycosylceramide ~~lipid or glycolipid~~, wherein the pathogenesis of the disease is derived from an inflammatory immune response.

2. (Withdrawn) A method for the treatment of a disease in a mammalian subject comprising administering to said subject an effective amount of a T cell ligand, wherein the T cell ligand is an intermediary metabolite.

3. (Withdrawn) A method of claim 1 wherein the result comprises the alteration of the metabolic profile of said subject.

4. (Withdrawn) The method of claim 1 wherein the result comprises an increase in glucose tolerance.

5. (Withdrawn) The method of claim 1 wherein the result comprises a reduction in liver fat content.

6. (Previously Presented) The method of claim 1 wherein the result of said administration comprises changes in cytokine responses.

7. (Withdrawn) An in vitro screening assay for an analogue or derivative of an intermediary metabolite which is administered to a mammalian subject to treat a disease comprising:

a) providing in vitro:

(i) regulatory, immune-regulatory or NKT cells from said subject or another subject;

(ii) antigen presenting cells;

(iii) analogue or derivative of said intermediary metabolite; and

b) identifying a decrease in said regulatory, immune-regulatory or NKT cell proliferation.

8. (Withdrawn) An in vitro screening assay for an analogue or derivative of an intermediary metabolite which is administered to a mammalian subject to treat a disease comprising:

a) providing in vitro:

i) regulatory, immune-regulatory or NKT cells and BSA in a first test tube;

ii) regulatory, immune-regulatory or NKT cells and said analogue or derivative of an intermediary metabolite in a second test tube;

iii) regulatory, immune-regulatory or NKT cells, antigen presenting cells and BSA in a third test tube;

iv) regulatory, immune-regulatory or NKT cells, antigen-presenting cells and an analogue or derivative of said intermediary metabolite;

b) determining the amount of regulatory, immune-regulatory or NKT cell proliferation in each of said tubes; and

c) identifying the least amount of regulatory, immune-regulatory or NKT cell proliferation in said fourth tube.

9. (Withdrawn) A method for treating a disease in a mammalian subject comprising:

a) obtaining cells from said subject or another subject, said cells comprising regulatory, immune-regulatory or NKT cells;

b) treating or educating said cells ex vivo in the presence of:

i) intermediary metabolite;

ii) antigens or epitopes associated with said disease, or antigens or epitopes associated with the immune-mediated inflammatory response; and

iii) antigen presenting cells; or

iv) any combination of the above; and

b) re-administering to said subject said treated or educated cells.

10. (Withdrawn) A method for treating a disease in a mammalian subject comprising:

a) obtaining cells from said subject or another subject, said cells comprising regulatory, immune-regulatory or NKT cells;

b) treating or educating said cells ex vivo in the presence of:

i) intermediary metabolite;

ii) antigens or epitopes associated with said disease, or antigens or epitopes associated with the immune-mediated inflammatory response; and

iii) antigen presenting cells; or

iv) any combination of the above;

c) re-administering to said subject said treated or educated cells; and

d) administering to said subject:

i) an effective amount of an intermediary metabolite;

ii) antigen presenting cells;

iii) antigens or epitopes associated with said disease, or antigens or epitopes associated with the immune-mediated inflammatory response; or

iv) any combination of the above.

11. (Currently Amended) A method for the treatment of a disease in a mammalian subject, wherein the pathogenesis of the disease is derived from an inflammatory immune response, the method comprising administering to said subject:

~~a)~~ an effective amount of a mammalian intermediary metabolite, wherein said intermediary metabolite is a β-glycosylceramide, and ~~lipid or glycolipid~~;

a~~b~~) antigen presenting cells;

b~~c~~) antigens or epitopes associated with said disease;~~, or~~

c) antigens or epitopes associated with the immune-mediated inflammatory response; or

d) any combination of ~~the above~~a), b) or c).

12. (Withdrawn) A therapeutic composition for the treatment of a disease in a mammalian subject comprising:

a) an intermediary metabolite;

b) antigen presenting cells;

c) antigens or epitopes associated with said disease, or antigens or epitopes associated with the immune-mediated inflammatory response; or

d) any combination of the above.

13. (Withdrawn) The method of claim 1, wherein said intermediary metabolite comprises a lipid or conjugated biomolecule.

14. (Withdrawn) The method of claim 1, wherein said intermediary metabolite comprises any polar lipid.

15. (Withdrawn) The method of claim 13 wherein said conjugated biomolecule comprises a glycolipid, lipoprotein, apolipoprotein, or glycoprotein other than antibodies, cytokines, or hormones.

16. (Withdrawn) The method of claim 15 wherein said glycolipid comprises a monosaccharide ceramide.

17. (Withdrawn) The method of claim 16 wherein said monosaccharide ceramide comprises a glucosylceramide or galactosylceramide.

18. (Withdrawn) The method of claim 17 wherein said glucosylceramide comprises glucocerebroside.

19. (Withdrawn) The method of claim 17 wherein said glucosylceramide comprises a glucocerebroside analogue or derivative.

20. (Withdrawn) The method of claim 11, wherein said antigens comprise allogeneic antigens obtained from donors suffering from said immune-related or immune-mediated disorder or disease, xenogenic antigens, syngeneic antigens, autologous antigens, non-autologous antigens, recombinantly prepared antigens, or any combination thereof.

21. (Withdrawn) The method of claim 11, wherein said antigen presenting cell comprises a dendritic cell or a CD1d receptor-presenting dendritic cell.

22. (Withdrawn) An in vitro screening assay for an analogue or derivative of a T cell receptor ligand that is an intermediary metabolite comprising:

a) providing in vitro:

(i) regulatory, immune-regulatory or NKT cells from said subject or another subject;

(ii) antigen presenting cells;

(iii) analogue or derivative of said T cell receptor ligand;

b) identifying a decrease in said regulatory, immune-regulatory or NKT cell proliferation.

23. (Withdrawn) An in vitro screening assay for an analogue or derivative of a T cell receptor ligand that is an intermediary metabolite, which is administered to a mammalian subject to treat a disease comprising:

a) providing in vitro:

i) regulatory, inunune-regulatory or NKT cells and BSA in a first test tube;

ii) regulatory, immune-regulatory or NKT cells and said analogue or derivative of a T cell receptor ligand in a second test tube;

iii) regulatory, immune-regulatory or NKT cells, antigen presenting cells and BSA in a third test tube;

iv) regulatory, immune-regulatory or NKT cells, antigen-presenting cells and an analogue or derivative of said T cell receptor ligand;

b) determining the amount of regulatory, immune-regulatory or NKT cell proliferation in each of said tubes; and

c) identifying the least amount of regulatory, immune-regulatory or NKT cell proliferation in said fourth tube.

24. (Withdrawn) A method for treating a disease in a mammalian subject comprising:

a) obtaining cells from said subject or another subject, said cells comprising regulatory, immune-regulatory or NKT cells;

b) treating or educating said cells ex vivo in the presence of:

i) T cell receptor ligand, wherein the T cell ligand is an intermediary metabolite;

ii) antigens or epitopes associated with said disease, or antigens or epitopes associated with the immune-mediated inflammatory response; and

iii) antigen presenting cells; or

iv) any combination of the above;

b) re-administering to said subject said treated or educated cells.

25. (Withdrawn) A method for treating a disease in a mammalian subject comprising:

a) obtaining cells from said subject or another subject, said cells comprising regulatory, immune-regulatory or NKT cells;

b) treating or educating said cells ex vivo in the presence of:

i) T cell receptor ligand, wherein the T cell ligand is an intermediary metabolite;

ii) antigens or epitopes associated with said disease, or antigens or epitopes associated with the immune-mediated inflammatory response; and

iii) antigen presenting cells; or

iv) any combination of the above;

c) re-administering to said subject said treated or educated cells; and

d) administering to said subject:

i) an effective amount of T cell receptor ligand;

ii) antigen presenting cells;

iii) antigens or epitopes associated with said disease, or antigens or epitopes associated with the immune-mediated inflammatory response; or

iv) any combination of the above.

26. (Withdrawn) A method for the treatment of a disease in a mammalian subject comprising administering to said subject:

a) an effective amount of T cell receptor ligand, wherein the T cell receptor ligands are intermediary metabolites;

b) antigen presenting cells;

c) antigens or epitopes associated with said disease, or antigens or epitopes associated with the immune-mediated inflammatory response; or

d) any combination of the above.

27. (Withdrawn) A therapeutic composition for the treatment of a disease in a mammalian subject comprising:

a) T cell receptor ligands, wherein the T cell receptor ligands are intermediary metabolites;

b) antigen presenting cells;

c) antigens or epitopes associated with said disease; or antigens or epitopes associated with the immune-mediated inflammatory response; or

d) any combination of the above.

28. (Withdrawn) The method of claim 2, wherein said T cell receptor ligand comprises a lipid or conjugated biomolecule.

29. (Withdrawn) The method of claim 2, wherein said T cell receptor ligand comprises any polar lipid.

30. (Withdrawn) The method of claim 28 wherein said conjugated biomolecule comprises a glycolipid, lipoprotein, apolipoprotein, or glycoprotein other than antibodies, cytokines, or hormones.

31. (Withdrawn) The method of claim 30 wherein said glycolipid comprises a monosaccharide ceramide.

32. (Withdrawn) The method of claim 31 wherein said monosaccharide ceramide comprises a glucosylceramide or galactosylceramide.

33. (Withdrawn) The method of claim 32 wherein said glucosylceramide comprises glucocerebroside.

34. (Withdrawn) The method of claim 32 wherein said glucosylceramide comprises a glucocerebroside analogue or derivative.

35. (Withdrawn) The method of claim 24, wherein said antigens comprise allogeneic antigens obtained from donors suffering from said immune-related or immune-mediated

disorder or disease, xenogenic antigens, syngeneic antigens, autologous antigens, non-autologous antigens, recombinantly prepared antigens, or any combination thereof.

36. (Withdrawn) The method of claim 24, wherein said antigen presenting cell comprises a dendritic cell or a CD1d receptor-presenting dendritic cell.

37. (Withdrawn) The method of claim 116, wherein said administering step comprises oral, intravenous, intraperitoneal, intramuscular, parenteral, transdermal, intravaginal, intranasal, mucosal, sublingual, topical, rectal or subcutaneous administration, or any combination thereof.

38. (Withdrawn) The method of claim 116, wherein said disease comprises Con-A Hepatitis, any type of viral mediated or immune drug mediated hepatitis, bacterial infections, viral infections, fungal infections, or parasitic infections.

39. (Withdrawn) The method of claim 38 wherein said viral infection comprises HBV, HCV or HIV.

40. (Withdrawn) The method of claim 116, wherein said disease comprises colitis, Inflammatory Bowel Disease, Ulcerative Colitis, Crohn's Disease, Systemic Lupus, Osteoporosis, Non-Alcoholic Steatohepatitis, Diabetes Mellitus, glucose intolerance, obesity, metabolic syndrome, Graft Versus Host Disease, Multiple Sclerosis, Rheumatoid Arthritis, JRA, Eye Disease, Uveitis, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease, Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, Myasthenia Gravis, non-HIV AIDS, (Systemic) Lupus Erythematosus, Juvenile Rheumatoid Arthritis, Idiopathic Thrombocytopenic Purpura, Scleroderma, Raynaud's Phenomenon, Mixed Connective Tissue Disorder, Celiac Disease, Crest Syndrome (Calcinosis Cutis, Raynaud's Phenomenon,

Esophageal Dysfunction, Sclerodactyly and Telangiectasis) or any other immune-related or immune-mediated disorder or disease.

41. (Withdrawn) The method of claim 116, wherein said disease comprises hyperlipidimia, atherosclerosis, primary pulmonary hypertension and all other types of hypertension, any type of ischemic heart disease, asthma, sarcoidosis, chronic lung disease, Alzheimer's Disease, any type of neurodegenerative disorders, cerebrovascular disease, or any other metabolic disorder.

42. (Withdrawn) The method of claim 116, wherein said disease comprises melanoma, any type of neoplastic disorder, any tumor growth, malignant or non-malignant, solid tumors, non-solid tumors, hepatocellular carcinoma, leukemia, lymphoma, or any other type of cancer.

43. (Currently Amended) A method for the treatment of a disease in a mammalian subject comprising administering to said subject an effective amount of a mammalian intermediary metabolite, wherein said intermediary metabolite is a β-glycosylceramide ~~lipid or glycolipid~~, wherein the pathogenesis of the disease is derived from an inflammatory immune response, the result of said administration comprising a change in the number or function of regulatory, immune-regulatory or NKT cells.

44. (Currently Amended) A method for the treatment of a disease in a mammalian subject comprising administering to said subject an effective amount of a mammalian intermediary metabolite, wherein said intermediary metabolite is a β-glycosylceramide ~~lipid or glycolipid~~, wherein the pathogenesis of the disease is derived from an inflammatory immune response, the result of said administration comprising the reduction, inhibition, or decrease of the number or function of regulatory, immune-regulatory or NKT cells.

45. (Currently Amended) A method for the treatment of a disease in a mammalian subject comprising administering to said subject an effective amount of a mammalian intermediary metabolite, wherein said intermediary metabolite is a β-glycosylceramide ~~lipid or glycolipid~~, wherein the pathogenesis of the disease is derived from an inflammatory immune response, the result of said administration comprising the stimulation or increase of the number or function of regulatory, immune-regulatory or NKT cells.

46. (Withdrawn) The method of claim 44 wherein said regulatory, immune-regulatory or NKT cells are intrahepatic NKT cells.

47. (Original) The method of claim 44 wherein said inhibition comprises the competitive displacement of activating elements from the CD1d molecule.

48. (Original) The method of claim 45 wherein said stimulation comprises the increased binding of activating elements from the CD1d molecule.

49. (Previously Presented) The method of claim 43, wherein said result further comprises changes in cytokine responses.

50. (Original) The method of claim 49 wherein said cytokines comprise IFNγ, IL2, IL4, IL 10, or IL12.

51. (Original) The method of claim 49 wherein said cytokine response comprises a pro-inflammatory, anti-inflammatory or both a pro-inflammatory and anti-inflammatory response.

52. (Previously Presented) The method of claim 43, wherein said result further comprises changes in the Thl/Th2 balance in said subject's immune system.

53. (Withdrawn) A method for the treatment of a disease in a mammalian subject comprising administering to said subject an effective amount of an intermediary metabolite and antigen presenting cells, the result of said administration comprising a decrease in regulatory, immune-regulatory or NKT cell proliferation.

54. (Currently Amended) A method for the treatment of a disease in a mammalian subject comprising administering to said subject an effective amount of a mammalian intermediary metabolite and antigen presenting cells, the result of said administration comprising an increase in regulatory, immune-regulatory or NKT cell proliferation, wherein said intermediary metabolite is a β-glycosylceramide ~~lipid or glycolipid~~, and wherein the pathogenesis of the disease is derived from an inflammatory immune response.

55. (Withdrawn) An in vitro screening assay for an analogue or derivative of an intermediary metabolite which is administered to a mammalian subject to treat a disease resulting in a change in the number of regulatory, immune-regulatory or NKT cells, said assay comprising:

a) providing in vitro:

(i) regulatory, immune-regulatory or NKT cells from said subject or another subject;

(ii) antigen presenting cells;

(iii) analogue or derivative of said intermediary metabolite;

b) identifying a decrease in said regulatory, immune-regulatory or NKT cell proliferation.

56. (Withdrawn) An in vitro screening assay for an analogue or derivative of an intermediary metabolite which is administered to a mammalian subject to treat a disease resulting in a change in the number of regulatory, immune-regulatory or NKT

cells, said assay comprising:

a) providing in vitro:

i) regulatory, immune-regulatory or NKT cells and BSA in a first test tube;

ii) regulatory, immune-regulatory or NKT cells and said analogue or derivative of an intermediary metabolite in a second test tube;

iii) regulatory, immune-regulatory or NKT cells, antigen presenting cells and BSA in a third test tube;

iv) regulatory, immune-regulatory or NKT cells, antigen-presenting cells and an analogue or derivative of said intermediary metabolite;

b) determining the amount of regulatory, immune-regulatory or NKT cell proliferation in each of said tubes; and

c) identifying the least amount of regulatory, immune-regulatory or NKT cell proliferation in said fourth tube.

57. (Withdrawn) A method for treating a disease in a mammalian subject comprising:

a) obtaining cells from said subject or another subject, said cells comprising regulatory, immune-regulatory or NKT cells;

b) treating or educating said cells ex vivo in the presence of:

i) intermediary metabolite;

ii) antigens or epitopes associated with said disease, or antigens or epitopes associated with the immune-mediated inflammatory response; and

iii) antigen presenting cells; or

iv) any combination of the above;

b) re-administering to said subject said treated or educated cells, the result of said administration comprising a change in the number of said cells.

58. (Withdrawn) A method for treating a disease in a mammalian subject comprising:

a) obtaining cells from said subject or another subject, said cells comprising

regulatory, immune-regulatory or NKT cells;

b) treating or educating said cells ex vivo in the presence of:

i) intermediary metabolite;

ii) antigens or epitopes associated with said disease, or antigens or epitopes associated with the immune-mediated inflammatory response; and

iii) antigen presenting cells; or

iv) any combination of the above;

c) re-administering to said subject said treated or educated cells;

d) administering to said subject:

i) an effective amount of an intermediary metabolite;

ii) antigen presenting cells;

iii) antigens or epitopes associated with said disease, or antigens or epitopes associated with the immune-mediated inflammatory response; or

iv) any combination of the above;

e) the result of said administration comprising a change in the number of regulatory cells, immune-regulatory cells or NKT cells.

59. (Currently Amended) A method for the treatment of a disease in a mammalian subject wherein the pathogenesis of the disease is derived from an inflammatory immune response, the method comprising administering to said subject:

~~a)~~ an effective amount of a mammalian intermediary metabolite, wherein said intermediary metabolite is a β-glycosylceramide ~~lipid or glycolipid~~; and

a~~b~~) antigen presenting cells;

b~~c~~) antigens or epitopes associated with said disease; ~~or~~

c) antigens or epitopes associated with the immune-mediated inflammatory response; or

d) any combination of ~~the above~~a), b) or c);

the result of said administration comprising a change in the number of regulatory cells, immune-regulatory cells or NKT cells.

60. (Currently Amended) A method for treating a disease in a mammalian subject wherein the pathogenesis of the disease is derived from an inflammatory immune response, comprising administering to said subject an effective amount of a mammalian intermediary metabolite, wherein said intermediary metabolite is a β-glycosylceramide ~~lipid or glycolipid~~, so as to modulate or change at least one component in the immune system of said subject.

61. (Withdrawn) A therapeutic composition for the treatment of a disease in a mammalian subject, the administration of said composition resulting in a change in the number of regulatory, immune-regulatory or NKT cells, said composition comprising:

a) an intermediary metabolite;

b) antigen presenting cells;

c) antigens or epitopes associated with said disease; or antigens or epitopes associated with the immune-mediated inflammatory response;

d) any combination of the above.

62. (Withdrawn) The composition of claim 61 wherein said result comprises the reduction, inhibition, or decrease in the number or function of said cells.

63. (Withdrawn) The composition of claim 61 wherein said result comprises the stimulation or increase in the number or function of said cells.

64. (Withdrawn) The use of an intermediary metabolite in the manufacture of a composition for the manipulation of regulatory, immune-regulatory or NKT cells in a mammalian subject suffering from a disease.

65. (Withdrawn) The method of claim 64 wherein said manipulation comprises a change in the number or function of said cells.

66. (Withdrawn) The method of claim 65 wherein said change comprises a reduction, inhibition or decrease of the number or function of said cells.

67. (Withdrawn) The method of claim wherein said change comprises a stimulation or increase in the number or function of said cells.

68. (Withdrawn) The method of claim 43, wherein said intermediary metabolite comprises a lipid or conjugated biomolecule.

69. (Withdrawn) The method of claim 43, wherein said intermediary metabolite comprises any polar lipid.

70. (Withdrawn) The method of claim 68 wherein said conjugated biomolecule comprises a glycolipid, lipoprotein, apolipoprotein, or glycoprotein other than antibodies, cytokines, or hormones.

71. (Withdrawn) The method of claim 70 wherein said glycolipid comprises a monosaccharide ceramide.

72. (Withdrawn) The method of claim 71 wherein said monosaccharide ceramide comprises a glucosylcerainide or galactosylceramide.

73. (Withdrawn) The method of claim 72 wherein said glucosylceramide comprises glucocerebroside.

74. (Withdrawn) The method of claim 72 wherein said glucosylceramide comprises a glucocerebroside analogue or derivative.

75. (Previously Presented) The method of claim 59, wherein said antigens comprise allogeneic antigens obtained from donors suffering from said immune-related or immune-mediated disorder or disease, xenogenic antigens, syngeneic antigens, autologous antigens, non-autologous antigens, recombinantly prepared antigens, or any combination thereof.

76. (Previously Presented) The method of claim 59, wherein said antigen presenting cell comprises a dendritic cell or a CD1 receptor-presenting dendritic cell.

77. (Withdrawn) The method of claim 43, wherein said disease is Con-A Hepatitis.

78. (Withdrawn) The method of claim 43, wherein said disease comprises any type of viral mediated or immune drug mediated hepatitis, bacterial infections, viral infections, fungal infections, or parasitic infections.

79. (Withdrawn) The method of claim 78 wherein said viral infection comprises HBV, HCV or HIV.

80. (Withdrawn) The method of claim 43, wherein said administering step comprises oral, intravenous, intraperitoneal, intramuscular, parenteral, transdermal, intravaginal, intranasal, mucosal, sublingual, topical, rectal or subcutaneous administration, or any combination thereof.

81. (Withdrawn) A method for the treatment of an immune-mediated or immune-related disorder or disease in a mammalian subject comprising administering to said subject an effective amount of an intermediary metabolite, the result of said administration comprising an alteration of the regulatory, immune-regulatory or NKT cell distribution in said subject.

82. (Withdrawn) A method for the treatment of an immune-mediated or immune-related disorder or disease in a mammalian subject comprising administering to said subject an effective amount of an intermediary metabolite, the result of said administration comprising an alteration of the regulatory, immune-regulatory or NIKT cell distribution in said subject and/or a change in the peripheral/intrahepatic T cell ratio.

83. (Withdrawn) The method of claim 82 wherein said change in the peripheral/intrahepatic T cell ratio comprises an increase in said ratio.

84. (Withdrawn) A method for the treatment of an immune-mediated or immune-related disorder or disease in a mammalian subject comprising administering to said subject an effective amount of an intermediary metabolite, the result of said administration comprising an alteration of the regulatory, immune-regulatory or NKT cell distribution in said subject and/or a change in intrahepatic CD8+ T cell trapping.

85. (Withdrawn) The method of claim 84 wherein said change in intrahepatic CD8+ T cell trapping comprises an increase in said trapping.

86. (Withdrawn) The method of claim 81, wherein said regulatory, immune-regulatory or NKT cells comprise intrahepatic or intrasplenic NKT cells.

87. (Withdrawn) The method of claim 81, or wherein said result further comprises changes in cytokine responses.

88. (Withdrawn) The method of claim 87 wherein said cytokines comprise IFNγ, TNFa, IL4, or IL10.

89. (Withdrawn) The method of claim 87 wherein said cytokine response comprises a pro-inflammatory, anti-inflammatory or both a pro-inflammatory and anti-inflammatory

response.

90. (Withdrawn) The method of claim any one of claims 81 to 85 wherein said result further comprises changes in the Th1/Th2 balance in said subject's immune system.

91. (Withdrawn) A method for the treatment of an immune-mediated or immune regulated disorder or disease in a mammalian subject comprising administering to said subject an effective amount of an intermediary metabolite and/or antigen presenting cells, the result of said administration comprising an alteration of the regulatory, immune-regulatory or NKT cell distribution.

92. (Withdrawn) A method for the treatment of an immune-mediated or immune regulated disorder or disease in a mammalian subject comprising administering to said subject an effective amount of an intermediary metabolite and/or antigen presenting cells, the result of said administration comprising an alteration of the function of the regulatory, immune-regulatory or NKT cell distribution.

93. (Withdrawn) An in vitro screening assay for an analogue or derivative of an intermediary metabolite which is administered to a mammalian subject to treat a disease resulting in an alteration of the regulatory, immune-regulatory or NKT cell distribution, said assay comprising:

a) providing in vitro:

(i) regulatory, immune-regulatory or NKT cells from said subject or another subject;

(ii) antigen presenting cells;

(iii) analogue or derivative of said intermediary metabolite;

b) identifying a decrease in said regulatory, immune-regulatory and NKT cell proliferation.

94. (Withdrawn) An in vitro screening assay for an analogue or derivative of an intermediary metabolite which is administered to a mammalian subject to treat a disease resulting in a change of the regulatory, immune-regulatory or NKT cell distribution, said assay comprising:

a) providing in vitro:

i) regulatory, immune-regulatory or NKT cells and BSA in a first test tube;

ii) regulatory, immune-regulatory or NKT cells and said analogue or derivative of an intermediary metabolite in a second test tube;

iii) regulatory, immune-regulatory or NKT cells, antigen presenting cells and BSA in a third test tube;

iv) regulatory, immune-regulatory or NKT cells, antigen-presenting cells and an analogue or derivative of said intermediary metabolite;

b) determining the amount of regulatory, immune-regulatory or NKT cell proliferation in each of said tubes; and

c) identifying the least amount of regulatory, immune-regulatory or NKT cell proliferation in said fourth tube.

95. (Withdrawn) A method for treating a disease in a mammalian subject comprising:

a) obtaining cells from said subject or another subject, said cells comprising regulatory, immune-regulatory or NKT cells;

b) treating or educating said cells ex vivo in the presence of:

i) intermediary metabolite;

ii) antigens or epitopes associated with said disease, or antigens or epitopes associated with the immune-mediated inflammatory response; and

iii) antigen presenting cells; or

iv) any combination of the above;

b) re-administering to said subject said treated or educated cells, the result of said administration comprising a change in said cell distribution.

96. (Withdrawn) A method for treating a disease in a mammalian subject comprising:

a) obtaining cells from said subject or another subject, said cells comprising regulatory, immune-regulatory or NKT cells;

b) treating or educating said cells ex vivo in the presence of:

i) intermediary metabolite;

ii) antigens or epitopes associated with said disease, or antigens or epitopes associated with the immune-mediated inflammatory response; and

iii) antigen presenting cells; or

iv) any combination of the above;

c) re-administering to said subject said treated or educated cells;

d) administering to said subject:

i) an effective amount of an intermediary metabolite;

ii) antigen presenting cells;

iii) antigens or epitopes associated with said disease, or antigens or epitopes associated with the immune-mediated inflammatory response; or

iv) any combination of the above;

the result of said administration comprising a change of the regulatory, immune-regulatory or NKT cell, distribution.

97. (Currently Amended) A method for the treatment of a disease in a mammalian subject, wherein the pathogenesis of the disease is derived from an inflammatory immune response, the method comprising administering to said subject:

~~a)~~ an effective amount of a mammalian intermediary metabolite, wherein said intermediary metabolite is a β-glycosylceramide ~~lipid or glycolipid~~; and

a~~b~~) antigen presenting cells;

b~~c~~) antigens or epitopes associated with said disease; ~~or~~

c) antigens or epitopes associated with the immune-mediated inflammatory response; or

d) any combination of ~~the above~~a), b) or c);

the result of said administration comprising a change of the regulatory, immune-regulatory or NKT cell distribution.

98. (Withdrawn) A method for treating a disease in a mammalian subject comprising administering to said subject an effective amount of an intermediary metabolite so as to modulate or change at least one component in the immune system of said subject.

99. (Withdrawn) A therapeutic composition for the treatment of a disease in a mammalian subject, the administration of said composition resulting in a change of the regulatory, immune-regulatory or NKT cell distribution, said composition comprising:

a) an intermediary metabolite;

b) antigen presenting cells;

c) antigens or epitopes associated with said disease; or antigens or epitopes associated with the immune-mediated inflammatory response; or

d) any combination of the above.

100. (Withdrawn) The use of an intermediary metabolite in the manufacture of a composition for the manipulation of regulatory, immune-regulatory or NKT cells in a mammalian subject suffering from an immune-related or immune-mediated disorder or disease.

101. (Withdrawn) The method of claim 100 wherein said manipulation comprises a change of the distribution of said cells in said subject.

102. (Withdrawn) The method of claim 97, wherein said intermediary metabolite comprises a lipid or conjugated biomolecule.

103. (Withdrawn) The method of claim 97, wherein said intermediary metabolite

comprises a polar lipid.

104. (Withdrawn) The method of claim 102 wherein said conjugated biomolecule comprises a glycolipid, lipoprotein, apolipoprotein, or glycoprotein other than antibodies, cytokines, or hormones.

105. (Withdrawn) The method of claim 104 wherein said glycolipid comprises a monosaccharide ceramide.

106. (Withdrawn) The method of claim 105 wherein said monosaccharide ceramide comprises a glucosylceramide or galactosylceramide.

107. (Withdrawn) The method of claim 106 wherein said glucosylceramide comprises glucocerebroside.

108. (Withdrawn) The method of claim 106 wherein said glucosylceramide comprises a glucocerebroside analogue or derivative.

109. (Previously Presented) The method of claim 97, wherein said antigens comprise allogeneic antigens obtained from donors suffering from said immune-related or immune-mediated disorder or disease, xenogenic antigens, syngeneic antigens, autologous antigens, non-autologous antigens, recombinantly prepared antigens, or any combination thereof.

110. (Withdrawn) The method of claim 97, wherein said antigen presenting cell comprises a dendritic cell or a CD1d receptor-presenting dendritic cell.

111. (Withdrawn) The method of claim 97, wherein said immune-mediated or immune-related disease or disorder comprises colitis.

112. (Withdrawn) The method of claim 97, wherein said disease comprises Inflammatory Bowel Disease, Ulcerative Colitis, Crohn's Disease, Systemic Lupus, Osteoporosis, Non-Alcoholic Steatohepatitis, Diabetes Mellitus, glucose intolerance, obesity, metabolic syndrome, Graft Versus Host Disease, Multiple Sclerosis, Rheumatoid Arthritis, JRA, Eye Disease, Uveitis, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease, Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, Myasthenia Gravis, non-HIV AIDS, (Systemic) Lupus Erythematosus, Juvenile Rheumatoid Arthritis, Idiopathic Thrombocytopenic Purpura, Scleroderma, Raynaud's Phenomenon, Mixed Connective Tissue Disorder, Celiac Disease, Crest Syndrome (Calcinosis Cutis, Raynaud's Phenomenon, Esophageal Dysfunction, Sclerodactyly and Telangiectasis) or any other immune-related or immune-mediated disorder or disease.

113. (Withdrawn) The method of claim 97, wherein said administering step comprises oral, intravenous, intraperitoneal, intramuscular, parenteral, transdermal, intravaginal, intranasal, mucosal, sublingual, topical, rectal or subcutaneous administration, or any combination thereof.

114. (Withdrawn) The method of claim 11, wherein said mammalian subject has been without food and/or water for a minimum of twelve hours prior to said administration, treatment or manipulation.

115. (Withdrawn) The method of claim 11, wherein said mammalian subject has been subjected to fasting for a minimum of twelve hours prior to said administration, treatment or manipulation.

116. (Withdrawn) The method of claim 3, wherein said glycolipid comprises a

monosaccharide ceramide.

117. (Withdrawn) The method of claim 4, wherein said glycolipid comprises a monosaccharide ceramide,

118. (Withdrawn) The method of claim 5, wherein said glycolipid comprises a monosaccharide ceramide.

119. (Canceled)

120. (Currently amended) The method of claim 1, wherein said β-glycosylceramide ~~lipid~~ comprises a monosaccharide ceramide~~polar lipid~~.

121. (Withdrawn) The method of claim 116, wherein said monosaccharide ceramide comprises a glucosylceramide or galactosylceramide.

122. (Withdrawn) The method of claim 117, wherein said monosaccharide ceramide comprises a glucosylceramide or galactosylceramide.

123. (Withdrawn) The method of claim 118, wherein said monosaccharide ceramide comprises a glucosylceramide or galactosylceramide.

124. (Canceled)

125. (Currently Amended) The method of claim 1, wherein said β-glycosylceramide ~~glycolipid~~ comprises a glucosylceramide or galactosylceramide ~~monosaccharide ceramide~~.

126. (Previously Presented) The method of claim 11, wherein said antigens comprise

allogeneic antigens obtained from donors suffering from said immune-related or immune-mediated disorder or disease, xenogenic antigens, syngeneic antigens, autologous antigens, non-autologous antigens, recombinantly prepared antigens, or any combination thereof.

127-128. (Canceled)

129. (Withdrawn) The method of claim 11, wherein said antigen presenting cell comprises a dendritic cell or a CD1d receptor-presenting dendritic cell.

130. (Withdrawn) The method of claim 126, wherein said antigen presenting cell comprises a dendritic cell or a CD1d receptor-presenting dendritic cell.

131. (Withdrawn) The method of claim 127, wherein said antigen presenting cell comprises a dendritic cell or a CD1d receptor-presenting dendritic cell.

132. (Withdrawn) The method of claim 128, wherein said antigen presenting cell comprises a dendritic cell or a CD1d receptor-presenting dendritic cell.

133. (Withdrawn) The method of claim 2, wherein the result comprises the alteration of the metabolic profile of said subject.

134. (Withdrawn) The method of claim 2, wherein the result comprises an increase in glucose tolerance.

135. (Withdrawn) The method of claim 2, wherein the result comprises a reduction in liver fat content.

136. (Withdrawn) The method of claim 2, wherein the result comprises changes in

cytokine responses.

137. (Withdrawn) The method of claim 133, wherein said glycolipid comprises a monosaccharide ceramide.

138. (Withdrawn) The method of claim 134, wherein said glycolipid comprises a monosaccharide ceramide.

139. (Withdrawn) The method of claim 135, wherein said glycolipid comprises a monosaccharide ceramide.

140. (Withdrawn) The method of claim 136, wherein said glycolipid comprises a monosaccharide ceramide.

141. (Withdrawn) The method of claim 137, wherein said monosaccharide ceramide comprises a glucosylceramide or galactosylceramide.

142. (Withdrawn) The method of claim 138, wherein said monosaccharide ceramide comprises a glucosylceramide or galactosylceramide.

143. (Withdrawn) The method of claim 139, wherein said monosaccharide ceramide comprises a glucosylceramide or galactosylceramide.

144. (Withdrawn) The method of claim 140, wherein said monosaccharide ceramide comprises a glucosylceramide or galactosylceramide.

145. (Withdrawn) The method of claim 141, wherein said glucosylceramide comprises a glucocerebroside analogue or derivative.

146. (Withdrawn) The method of claim 142, wherein said glucosylceramide comprises a glucocerebroside analogue or derivative.

147. (Withdrawn) The method of claim 143, wherein said glucosylceramide comprises a glucocerebroside analogue or derivative.

148. (Withdrawn) The method of claim 144, wherein said glucosylceramide comprises a glucocerebroside analogue or derivative.

149. (Withdrawn) The method of claim 26, wherein said antigens comprise allogeneic antigens obtained from donors suffering from said immune-related or immune-mediated disorder or disease, xenogenic antigens, syngeneic antigens, autologous antigens, non-autologous antigens, recombinantly prepared antigens, or any combination thereof.

150. (Withdrawn) The method of claim 149, wherein said antigen presenting cell comprises a dendritic cell or a CD1d receptor-presenting dendritic cell.

151. (Previously Presented) The method of claims 1, 11, 43, 44, 45, 54, 59, 60 or 97 wherein said administering step comprises oral, intravenous, intraperitoneal, intramuscular, parenteral, transdermal, intravaginal, intranasal, mucosal, sublingual, topical, rectal or subcutaneous administration, or any combination thereof.

152-153. (Canceled)

154. (Withdrawn) The method of claim 150, wherein said administering step comprises oral, intravenous, intraperitoneal, intramuscular, parenteral, transdermal, intravaginal, intranasal, mucosal, sublingual, topical, rectal or subcutaneous administration, or any combination thereof.

155. (Withdrawn) The method of claim 11, wherein said disease comprises Con-A Hepatitis, any type of viral mediated or immune drug mediated hepatitis, bacterial infections, viral infections, fungal infections, or parasitic infections.

156. (Withdrawn) The method of claim 155, wherein said viral infection comprises HBV, HCV or HIV.

157. (Previously Presented) The method of claims 1, 11, 43, 44, 45, 54, 59, 60 or 97 wherein said disease comprises colitis, Inflammatory Bowel Disease, Ulcerative Colitis, Crohn's Disease, Systemic Lupus, Osteoporosis, Non-Alcoholic Steatohepatitis, Diabetes Mellitus, glucose intolerance, obesity, metabolic syndrome, Graft Versus Host Disease, Multiple Sclerosis, Rheumatoid Arthritis, JRA, Eye Disease, Uveitis, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease, Vasculitis, Scleroderma, CREST, Neurologic Disease, Lung Disease, Myositis, Ear Disease, Myasthenia Gravis, non-HIV AIDS, (Systemic) Lupus Erythematosus, Juvenile Rheumatoid Arthritis, Idiopathic Thrombocytopenic Purpura, Scleroderma, Raynaud's Phenomenon, Mixed Connective Tissue Disorder, Celiac Disease, Crest Syndrome (Calcinosis Cutis, Raynaud's Phenomenon, Esophageal Dysfunction, Sclerodactyly and Telangiectasis) or any other immune-related or immune-mediated disorder or disease.

158. (Withdrawn) The method of claim 11, wherein said disease comprises hyperlipidimia, atherosclerosis, primary pulmonary hypertension and all other types of hypertension, any type of ischemic heart disease, asthma, sarcoidosis, chronic lung disease, Alzheimer's Disease, any type of neurodegenerative disorders, cerebrovascular disease, or any other metabolic disorder.

159. (Withdrawn) The method of claim 11, wherein said disease comprises melanoma, any type of neoplastic disorder, any tumor growth, malignant or non-malignant, solid

tumors, non-solid tumors, hepatocellular carcinoma, leukemia, lymphoma, or any other type of cancer.

160. (Withdrawn) The method of claim 45, wherein said regulatory, immune-regulatory or NKT cells are intrahepatic NKT cells.

161. (Previously Presented) The method of claim 44, wherein said result further comprises changes in cytokine responses.

162. (Previously Presented) The method of claim 45, wherein said result further comprises changes in cytokine responses.

163. (Previously Presented) The method of claim 44, wherein said result further comprises changes in the Thl/Th2 balance in said subject's immune system.

164. (Previously Presented) The method of claim 45, wherein said result further comprises changes in the Thl/Th2 balance in said subject's immune system.

165. (Previously Presented) The method of claim 161, wherein said cytokines comprise IFNγ, IL2, IL4, IL10 or IL12.

166. (Previously Presented) The method of claim 162, wherein said cytokines comprise IFNγ, IL2, IL4, IL10 or IL12.

167. (Previously Presented) The method of claim 161, wherein said cytokine response comprises pro-inflammatory, anti-inflammatory or both a pro-inflammatory and anti-inflammatory response.

168. (Previously Presented) The method of claim 162, wherein said cytokine response

comprises pro-inflammatory, anti-inflammatory or both a pro-inflammatory and anti-inflammatory response.

169. (Previously Presented) The method of claim 125, wherein said monosaccharide ceramide comprises a glucosylceramide or galactosylceramide.

170. (Canceled)

171. (Withdrawn) The method of claim 60, wherein said antigen presenting cell comprises a dendritic cell or a CD1 receptor-presenting dendritic cell.

172. (Withdrawn) The method of claim 44, wherein said disease comprises any type of viral mediated or immune drug mediated hepatitis, bacterial infections, viral infections, fungal infections, or parasitic infections.

173. (Withdrawn) The method of claim 45, wherein said disease comprises any type of viral mediated or immune drug mediated hepatitis, bacterial infections, viral infections, fungal infections, or parasitic infections.

174. (Withdrawn) The method of claim 59, wherein said disease comprises any type of viral mediated or immune drug mediated hepatitis, bacterial infections, viral infections, fungal infections, or parasitic infections.

175. (Withdrawn) The method of claim 60, wherein said disease comprises any type of viral mediated or immune drug mediated hepatitis, bacterial infections, viral infections, fungal infections, or parasitic infections.

176. (Withdrawn) The method of claim 75, wherein said disease comprises any type of viral mediated or immune drug mediated hepatitis, bacterial infections, viral infections,

fungal infections, or parasitic infections.

177. (Withdrawn) The method of claim 76, wherein said disease comprises any type of viral mediated or immune drug mediated hepatitis, bacterial infections, viral infections, fungal infections, or parasitic infections.

178-182. (Canceled)

183. (Withdrawn) The method of claim 76, wherein said administering step comprises oral, intravenous, intraperitoneal, intramuscular, parenteral, transdermal, intravaginal, intranasal, mucosal, sublingual, topical, rectal or subcutaneous administration, or any combination thereof.

184. (Currently Amended) The method of claims 1, 11, 43, 44, 45, 54, 59, 60 or 97 wherein said disease~~immune-mediated or immune-related disease or disorder~~ comprises colitis.

185. (Withdrawn) The method of claim 110, wherein said immune-mediated or immune-related disease or disorder comprises colitis.

186. (Canceled)

187. (Withdrawn) The method of claim 110, wherein said disease comprises Inflammatory Bowel Disease, Ulcerative Colitis, Crohn's Disease, Systemic Lupus, Osteoporosis, Non-Alcoholic Steatohepatitis, Diabetes Mellitus, glucose intolerance, obesity, metabolic syndrome, Graft Versus Host Disease, Multiple Sclerosis, Rheumatoid Arthritis, JRA, Eye Disease, Uveitis, Skin Disease, Renal Disease, Hematologic Disease, ITP, PA, Autoimmune Liver Disease, Other Rheumatologic Disease, Endocrine Disease, Vasculitis, Scleroderma, CREST, Neurologic Disease,

Lung Disease, Myositis, Ear Disease, Myasthenia Gravis, non-HIV AIDS, (Systemic) Lupus Erythematosus, Juvenile Rheumatoid Arthritis, Idiopathic Thrombocytopenic Purpura, Scleroderma, Raynaud's Phenomenon, Mixed Connective Tissue Disorder, Celiac Disease, Crest Syndrome (Calcinosis Cutis, Raynaud's Phenomenon, Esophageal Dysfunction, Sclerodactyly and Telangiectasis) or any other immune-related or immune-mediated disorder or disease.

188. (Canceled)

189. (Withdrawn) The method of claim 110, wherein said administering step comprises oral, intravenous, intraperitoneal, intramuscular, parenteral, transdermal, intravaginal, intranasal, mucosal, sublingual, topical, rectal or subcutaneous administration, or any combination thereof.

190. (Withdrawn) The method of claim 26, wherein said mammalian subject has been without food and/or water for a minimum of twelve hours prior to said administration, treatment or manipulation.

191. (Previously Presented) The method of claims 1, 11, 43, 44, 45, 54, 59, 60 or 97 wherein said mammalian subject has been without food and/or water for a minimum of twelve hours prior to said administration, treatment or modulation.

192-196. (Canceled)

197. (Withdrawn) The method of claim 117, wherein said administering step comprises oral, intravenous, intraperitoneal, intramuscular, parenteral, transdermal, intravaginal, intranasal, mucosal, sublingual, topical, rectal or subcutaneous administration, or any combination thereof.

198. (Withdrawn) The method of claim 118, wherein said administering step comprises oral, intravenous, intraperitoneal, intramuscular, parenteral, transdermal, intravaginal, intranasal, mucosal, sublingual, topical, rectal or subcutaneous administration, or any combination thereof.

199. (Canceled)

200. (Withdrawn) The method of claim 116, wherein said immune-mediated or immune-related disease or disorder comprises colitis.

201. (Withdrawn) The method of claim 117, wherein said immune-mediated or immune-related disease or disorder comprises colitis.

202. (Withdrawn) The method of claim 118, wherein said immune-mediated or immune-related disease or disorder comprises colitis.

203-205. (Canceled)